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PATENT Customer No. 22,852 Attorney Docket No. **6832.0017** 

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)
Craig A. ROSEN et al.	) Group Art Unit: 1653
Application No.: 09/833,118	) Examiner: Hope A. Robinson
Filed: April 12, 2001	)
For: ALBUMIN FUSION PROTEINS	)

Mail Stop RCE

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

#### **CORRECTION OF INFORMATION DISCLOSURE STATEMENT FILED MAY 12, 2004**

An unsigned Information Disclosure Statement attaching a 44 page-PTO-1449 was inadvertently filed on May 12, 2004, concurrently with a Request for Continued Examination. The signed Information Disclosure Statement is being filed herewith. The associated 44-page PTO-1449 is also enclosed. Please associate the copies of the documents (4 boxes of references) that were filed on May 12, 2004, with the attached PTO-1449 and the signed Information Disclosure Statement. The original Information Disclosure Statement was filed pursuant to 37 C.F.R. §§ 1.56 and 1.97(b) and before the mailing date of a first Office Action on the merits for the above-referenced application following the Request for Continued Examination under 37 C.F.R. § 1.114.

Attorney Docket No. 6832.0017 Application No. 09/833,118

Even in the event that this Information Disclosure Statement is not accorded a filing date of May 12, 2004, the treatment of the Request for Continued Examination, also filed on May 12, 2004, should not be affected. The Request for Continued Examination was filed with the required fee, a signed Supplemental Information Disclosure Statement in addition to the unsigned Information Disclosure Statement, PTO-1449 (1 page) associated with the Supplemental Information Disclosure Statement, and copies of the 8 references listed on the PTO-1449. Thus, the submission requirement under 37 C.F.R. § 1.114 was satisfied.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

By: Charles E. Van Horn
Reg. No. 40,266

Dated: May 19, 2004



PATENT Customer No. 22,852

Attorney Docket No. 6832.0017

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Craig A. ROSEN et al.	) Group Art Unit: 1653
Application No.: 09/833,118	) Examiner: Hope A. Robinson
Filed: April 12, 2001	) )
For: ALBUMIN FUSION PROTEINS	)
	)

Mail Stop RCE

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

#### **INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)**

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application, following the concurrently filed Request for Continued Examination under 37 C.F.R. § 1.114.

Copies of the listed documents are attached.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

English translations of the following non-English patent documents are enclosed with the relevant documents:

JP 2 227079 JP 3 201987 WO 93/00437 WO 93/15200 WO 95/30759 WO 99/15193

English translations of the following non-English articles are also enclosed with the relevant documents:

Becquart, J., "Les Syncopes ou Malaises D'Origine Vasculaire," Soins, 504: 4-8 (1987).

Becquart J., et al., "Pronostic du Syndrome de Wolff-Parkinson-White chez le Nourrisson," *Arch. Mal. Coeur* 81:695-700 (1988).

Becquart, J., et al., "Insuffisance Aortique Argue Rhumatoide Traitee Par un Remplacement Valvulaire," Arch. Mal. Coeur 84:987-989 (1991).

Becquart, J., et al., "Les Pheochromocytomes Malins," Annales De Cardiologie Et D'Andeliologie, 36:191-196 (1987).

Cai, M. et al., "Development and Application of Hybridoma Secreting Monoclonal Antibody Against Poly-Human Serum Albumin" *J. WCUMS* 20(2):134-136 (1989).

Chen, Y-M., "Pulmonary Nocardiosis with Cerebral Abscess Successfully Treated by Medication Alone—A Case Report," *Chin. Med. J. (Taipei)* 47:294-298 (1991).

Chen, Y-M., et al., "Neurofibromatosis with Interstitial Pulmonary Fibrosis—Case Report and Literature Review," *Chin. Med. J. (Taipei)* 42:213-218 (1988).

Chen, Z., et al., "Enhancing the Immunogenicity of the preS Antigen of Hepatitis B Virus by Genetically Fusing it with Interleukin-2," *Natl. Med. J. China* 76(1):34-37 (1996).

Dmitrenko, V.V., et al., "Heterogeneity of the Polyadenylation Site of mRNA Coding for Human Serum Albumin," *Genetika* 26(4):765-769 (1990).

Fedorchenko, S.V., et al., "Is it Possible to Overcome Resistance of Patients with Chronic Hepatitis B to Antiviral Therapy Because of Production of Antibodies to Recombinant α<sub>2</sub>-Interferon?" *Voporsy Virusologii* 5:218-220 (1994).

Hannebicque, G., et al., "Manifestations Cardiaques De La Maladie De Lyme," *Ann. Cardiol. Angelol.* 38:87-90 (1989).

Huang S-Z., et al., "A Study of Transgenic IFV Cattle with the Human Serum Albumin Gene Integrated," *ACTA Genetic Sinica* 27(7):573-579 (2000).

Hwang, G-S., et al., "Small Bowel Perforation Secondary to Metastatic Pulmonary Carcinoma," *Chin. Med. J. (Taipei)* 41(2):159-164 (1988).

Le Bras, M., et al., "Epidemiologie et Clinique des Maladies Tropicales D'importation," La Revue de Medicine Interne 13:205-210 (1992).

Matsuda, Y., et al., "Human Serum Albumin Variants," *Tanpakushitu Kakusan Koso* 33(5):930-935 (1988).

Ohtani, W., et al., "Structure of Tecombinant Human Serum Albumin from *Pichia pastoris*," *J. Pharm. Soc. Japan* 117(4):220-232 (1997).

Ruzgas, T.A., et al., "Ellipsometric Study of Antigen-Antibody Interaction at the Interface Solid/Solution," *Biofizika*, 37 (1): 56-61 (1992).

Takeshima, K., et al., "Ligand Binding Properties and Esterase-like Activity of Recombinant Human Serum Albumin," *Regular Articles Yakugaku Zasshi* 116(8):622-629 (1996).

Thery, C., et al., "Filter Cave Temporaire Permettant le Diagnostic et al Fibrinolyse Chez les Patients Suspects d'embolie Pulmonaire Massive," *Arch. Mal. Coeur* 84:525-530 (1991).

Vincent, M.P., et al., "Surdosage a l'halofantrine," La Presse Medicale 3:131 (1992).

Yeh, P-F., et al., "Haemophilus Infection in Chronic Obstructive Pulmonary Disease Patients," *Chin. Med. J. (Taipei)*, 44:57-60 (1989).

Yeh, P-F., et al., "Tuberculosis Bacteremia," *China Med. J. (Taipei)* 47(4):290-293 (1991).

Zhong, S., et al., "Experimental Research on Inhibition of Hepatitis B Virus of Targeted Hepatocytes In Vitro by Antisense Oligonucleotides," *National Medical Journal of China* 75(7):392-395 (1995).

Zhou, C.S., et al., "A Monoclonal Antibody Directed Against an Enediyne Antitumor Antibiotic and its Preliminary Application," *ACTA Pharmaceutica Sinica* 32(1):28-32 (1997).

In lieu of English translations and as a concise statement of relevance of each,
English language Derwent abstracts of the following non-English patent documents are
enclosed with the following documents:

In lieu of a translation or statement of relevance, English-language patent equivalents and patent family information have been submitted for the following non-English patent documents:

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EP 0 236 210 A1 (equivalent to U.S. Pat. Nos., 5,100,784 and 5,187,261) EP 0 511 912 A1 (equivalent to U.S. Pat. No. 5,646,012) EP 0 711 835 A1 (equivalent to U.S. Pat. No. 6,114,146) FR 2,635,115 (equivalent to EP 0 361 991 A2) FR 2,719,593 (equivalent to WO 95/30759, translated as above) DE 37 23 781 A1 (equivalent to UK Pat. No. GB 2 193 631 A) WO 93/15199 (equivalent to U.S. Pat. No. 5,876,969) WO 93/15211 (equivalent to U.S. Pat. No. 5,665,863) WO 96/14409 (equivalent to AU Pat. No. 704,594) WO 96/14416 (equivalent to U.S. Pat. No. 6,149,911)
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Finally, the following U.S. patent applications are already before the Examiner and have been considered. Therefore, the following applications are being cited to place them on record:

09/832,501

Ballance et al.

Filed 4/12/01

Attorney Docket No. 6832.0017 Application No. 09/833,118

09/832,929	Rosen et al.	Filed 4/12/01
09/833,041	Rosen et al.	Filed 4/12/01
09/833,111	Rosen et al.	Filed 4/12/01
09/833,117	Rosen et al.	Filed 4/12/01

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

By: Charle E Van Hon #40266 for Lara C. Kelley

Dated: May 12, 2004



Atty. Docket No.	06832.0017-00000	Serial No.	09/833,118
Applicant	Craig A. ROSEN et al.		
Filing Date	April 12, 2001	Group:	1653

U.S. PATENT DOCUMENTS						
Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	4,336,248	06/22/82	Bonhard et al.	424	101	
	4,751,180	06/14/88	Cousens et al.	435	68	
	4,765,980	08/23/88	DePrince et al.	424	108	-
	4,801,575	01/31/89	Pardridge et al.	514	4	
· · · · · · · · · · · · · · · · · · ·	4,914,027	04/03/90	Knapp et al.	435	69.6	
	4,959,314	09/25/90	Mark et al.	435	69.1	
	4,970,300	11/13/90	Fulton et al.	530	383	
	5,045,312	09/03/91	Aston et al.	424	85.8	
	5,073,627	12/17/91	Curtis et al.	530	351	
·	5,100,784	03/31/92	Latta et al.	435	69.7	
	5,116,944	05/26/92	Sivam et al.	530	362	
	5,116,964	5/26/92	Capon et al.	536	23.5	
	5,187,261	02/16/93	Latta et al.	530	363	
	5,223,408	6/29/93	Goeddel et al.	435	69.3	
	5,272,070	12/21/93	Lehrman et al.	435	172.1	
	5,302,697	04/12/94	Goodey et al.	530	325	
	5,330,971	07/19/94	Wells et al.	514	2	
	5,336,603	08/09/94	Capon et al.	435	69.7	
	5,380,712	01/10/95	Ballance et al.	514	12	
	5,612,196	03/18/97	Becquart et al.	435	69.6	
	5,641,663	6/24/97	Garvin et al.	435	172.1	

Examiner		Date Considered
*Examiner:		considered, whether or not citation is in conformance with MPEP 609; draw line not in conformance and not considered. Include copy of this form with next applicant.
Form PTO 14	149	Patent and Trademark Office - U.S. Department of Commerce



Atty. Docket No.	06832.0017-00000	Serial No.	09/833,118
Applicant	Craig A. ROSEN et al.		
Filing Date	April 12, 2001	Group:	1653

	U.S. PATENT DOCUMENTS					
Examiner Initial*	Document Number	Issue Date	Name	Class	Sub Class	Filing Date If Appropriate
	5,646,012	07/08/97	Fleer et al.	435	69.1	
	5,665,863	09/09/97	Yeh et al.	530	351	
	5,679,777	10/21/97	Anderson et al.	530	385	
	5,705,363	01/06/98	Imakawa et al.	435	69.51	
-	5,714,377	02/02/98	Tanner et al.	435	254.11	·
	5,766,883	6/16/98	Ballance et al.	435	69.7	
	5,844,095	12/1/98	Linsley et al.	530	387.3	
	5,876,969	03/02/99	Fleer et al.	435	69.7	
	5,889,144	03/30/99	Alila et al.	530	300	
	5,948,428	09/07/99	Lee et al.	424	426	
	5,968,510	10/19/99	Linsley et al.	424	141.1	
	5,977,318	11/2/99	Linsley et al.	530	388.0	
	5,981,474	11/9/99	Manning et al.	514	2	
	6,114,146	09/05/00	Herlitschka et al.	435	69.7	
	6,149,911	11/21/00	Binz et al.	424	192.1	·
	6,165,470	12/26/00	Becquart et al.	424	185.1	
	6,514,500	2/4/03	Bridon et al.	424	193.1	
	6,686,179	2/3/04	Fleer et al.	435	69.7	
	2004-0010134 A1		Rosen et al.			4/12/01

Examiner		Date Considered
*Examiner:	Initial if reference control through citation if no communication to a	onsidered, whether or not citation is in conformance with MPEP 609; draw line of in conformance and not considered. Include copy of this form with next applicant.
Form PTO 14	449	Patent and Trademark Office - U.S. Department of Commerce



Atty. Docket No.	06832.0017-00000	Serial No.	09/833,118
Applicant	Craig A. ROSEN et al.		
Filing Date	April 12, 2001	Group:	1653

 2003-0104578 A1 (and pending claims)	Ballance	10/26/01
10/702,536 (and pending claims)	Fleer et al.	11/7/03
10/702,636 (and pending claims)	Fleer et al.	11/7/03
2003-0054554 A1	Becquart et al.	3/20/03 (publication date)
2003-0082747 A1	Fleer et al.	5/1/03 (publication date)
2003-0022308 A1	Fleer et al.	1/30/03 (publication date)
 2003-0036170 A1	Fleer et al.	2/20/03 (publication date)
2003-0036171 A1	Fleer et al.	2/20/03 (publication date)
2003-0036172 A1	Fleer et al.	2/20/03 (publication date)
 09/832,501	Ballance et al.	4/12/01
09/832,929	Rosen et al.	4/12/01
 09/833,041	Rosen et al.	4/12/01
09/833,111	Rosen et al.	4/12/01
09/833,117	Rosen et al.	4/12/01

FOREIGN PATENT DOCUMENTS						
	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No

Examiner		Date Considered
*Examiner: Initial if reference considered, whether or r through citation if not in conformance and communication to applicant.		nsidered, whether or not citation is in conformance with MPEP 609; draw line t in conformance and not considered. Include copy of this form with next opplicant.
Form PTO 14	149	Patent and Trademark Office - U.S. Department of Commerce



Atty. Docket No.	06832.0017-00000	Serial No.	09/833,118
Applicant	Craig A. ROSEN et al.		
Filing Date	April 12, 2001	Group:	1653

	FOREIGN PATE	NT DOCUMENT	s		
Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
0 073 646 A2	03/09/83	EPO			
0 079 739 A2	05/25/83	EPO			
0 088 632 A2	09/14/83	EPO			
0 091 527 A2	10/19/83	EPO			
0 116 201 A1	08/22/84	EPO			
0 123 294 A1	10/31/84	EPO			
0 123 544 A2	10/31/84	EPO			
0 138 437 A2	04/24/85	EPO			
0 147 198 A3	07/03/85	EPO			
0 163 406 A1	12/04/85	EPO			
 0 196 056 B1	10/01/86	EPO			
0 201 239 A1	11/12/86	EPO			
0 206 733 A1	12/30/86	EPO			
0 241 435 A2	10/14/87	EPO			
0 236 210 A1	09/09/87	EPO			English Equivalent
0 244 221 A1	11/04/87	EPO			
0 300 466 B1	9/13/95	EPO			
0 301 670 A1	02/01/89	EPO			
0 308 381 A1	03/22/89	EPO			
0 314 317 A1	05/03/89	EPO			
0 319 641 A1	06/14/89	EPO			

Examiner		Date Considered
		nsidered, whether or not citation is in conformance with MPEP 609; draw line in conformance and not considered. Include copy of this form with next plicant.
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Filing Date	April 12, 2001	Group:	1653

- 1.0-20-2-1-	, <u> </u>	FOREIGN PATE	NT DOCUMENTS	<b>S</b>		
	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	0 322 094 A1	06/28/89	EPO			
	0 325 262 A2	07/26/89	EPO			
	0 330 451 A2	08/30/89	EPO			
	0 344 459 A2	12/06/89	EPO			
	0 361 991 A2	04/04/90	EPO			
	0 364 980 B1	04/14/93	EPO			
	0 366 400 A2	05/02/90	EPO			
	0 395 918 A2	11/07/90	EPO			
	0 399 666 B1	11/28/90	EPO			
	0 401 384 B1	3/13/96	EPO			
	0 413 622 B1	02/20/91	EPO			
	0 416 673 A1	03/13/91	EPO			
	0 503 583 A1	09/16/92	EPO			
	0 509 841 A2	10/21/92	EPO			
	0 510 678 A2	10/28/92	EPO			
	0 510 693 A2	10/28/92	EPO			
	0 511 912 A1	11/4/92	EPO			English Equivalent
	0 711 835 A1	05/15/96	EPO			English Equivalent
	0 771 871 A2	07/5/97	EPO			
	1 117790	05/10/89	Japan			Abstract
	1235981A	11/24/99	China			Abstract

Examiner		Date Considered
		nsidered, whether or not citation is in conformance with MPEP 609; draw line in conformance and not considered. Include copy of this form with next opplicant.
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Atty. Docket No.	06832.0017-00000	Serial No.	09/833,118
Applicant	Craig A. ROSEN et al.		
Filing Date	April 12, 2001	Group:	1653

	FOREIGN PATE	NT DOCUMENTS	s		
Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
1239103A	12/22/99	China			Abstract
2 117384	05/01/90	Japan			Abstract
2 193 631 A	02/17/88	UK			
2 227079	09/10/90	Japan			Yes
2 350 362 A	11/29/00	UK			
2 635 115	09/06/90	France			English Equivalent
2 719 593	11/10/95	France			English Equivalent
2022539	02/04/91	Canada			
3 201987	09/03/91	Japan			Yes
3 27320	02/5/91	Japan			Abstract
37 23 781 A1	01/21/88	Germany			English Equivalent
4 211375	08/03/92	Japan			Abstract
5 292972	11/09/93	Japan			Abstract
6 38771	02/15/94	Japan			Abstract
6-22784	02/01/94	Japan			Abstract
704594	05/31/95	Australia			
8 53500	02/27/96	Japan			Abstract
8 59509	03/05/96	Japan			Abstract
8-51982	02/27/96	Japan			Abstract
WO 00/04171	01/27/00	PCT			
WO 00/23459	04/27/00	PCT			

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		nce considered, whether or not citation is in conformance with MPEP 609; draw line if not in conformance and not considered. Include copy of this form with next in to applicant.
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FOREIGN PATENT DOCUMENTS							
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	WO 00/44772	08/3/00	PCT				
	WO 87/03887	07/02/87	PCT				
	WO 89/02922	04/06/89	PCT				
	WO 90/04788	05/03/90	PCT				
	WO 90/13653	11/15/90	PCT				
	WO 91/02754	03/07/91	PCT				
	WO 91/08220	06/13/91	PCT				
	WO 93/00109	01/07/93	PCT				
	WO 93/00437	01/07/93	PCT			Yes	
	WO 93/03164	02/18/93	PCT				
	WO 93/15199	08/5/93	PCT			English Equivalent	
	WO 93/15200	08/05/93	PCT			Yes	
	WO 93/15211	08/05/93	PCT			English Equivalent	
	WO 94/25489	11/10/94	PCT				
	WO 95/23857	09/08/95	PCT				
	WO 95/27059	10/12/95	PCT				
	WO 95/30759	11/16/95	PCT			Yes	
	WO 96/03144 A1	02/08/96	PCT				
	WO 96/08512	03/21/96	PCT				
	WO 96/14409	05/17/96	PCT			English Equivalent	
	WO 96/14416	05/17/96	PCT			English Equivalent	

Examiner		Date Considered
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	FOREIGN PATENT DOCUMENTS					
	Document Number	Publication Date	Country	Class	Sub Class	Translation Yes or No
	WO 96/18412	06/20/96	PCT			
	WO 97/24445	07/10/97	PCT			
	WO 97/34997	09/25/97	PCT		1	
	WO 97/39132	10/23/97	PCT			
	WO 98/04718	02/05/98	PCT			
	WO 98/36085	08/20/98	PCT			
	WO 99/00504	01/07/99	PCT			
	WO 99/13914	03/25/99	PCT			
-	WO 99/15193	04/1/99	PCT			Yes
	WO 99/66054	12/23/99	PCT			
	WO 02/46227	6/13/02	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)				
	Abastado, J-P., et al., "A Soluble, Single Chain K <sup>d</sup> Molecule Produced by Yeast Selects a Peptide Repertoire Indistinguishable from that of Cell-surface-associated K <sup>d</sup> ," <i>Eur. J. Immunol.</i> , 23:1776-1783 (1993).			
	Ahluwalia, M., et al., "Isolation and Characterization of an Anticryptococcal Protein in Human Cerebrospinal Fluid," <i>J. Med. Microbiol.</i> 50:83-89 (2001).			
	Akiyama, Y., et al., "Characterization of a Human Blood Monocyte Subset with Low Peroxidase Activity," <i>The Journal of Clinical Investigation</i> 72:1093-1105 (1983).			
	Anonymous. "Use of Recombinant Human Albumin in the Formulation of Proteins," Research Disclosure, 516 August 1995.			
	Anspach, F.B., et al., "High-Performance Liquid Chromatography of Amino Acids, Peptides and Proteins," <i>Journal of Chromatography</i> 476:205-225 (1989).			

Examiner Date Considered		Date Considered
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		conformance and not considered. Include copy of this form with next
Form PTO 14	49	Patent and Trademark Office - U.S. Department of Commerce



Atty. Docket No.		Serial No.	09/833,118
Applicant	Craig A. ROSEN et al.		
Filing Date	April 12, 2001	Group:	1653

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
Armstrong, J.D., et al., "Active Immunization of Pigs Against Growth Hormone-Releasing Factor: Effect on Concentrations of Growth Hormone and Insulin-Like Growth Factor," <i>J. Anim. Sci.</i> 68:427-434 (1990).
Armstrong, J.D., et al., "Concentrations of Hormones and Metabolites, Estimates of Metabolism, Performance, and Reproductive Performance of Sows Actively Immunized Against Growth Hormone-Releasing Factor," <i>J. Anim. Sci.</i> 72:1570-1577 (1994).
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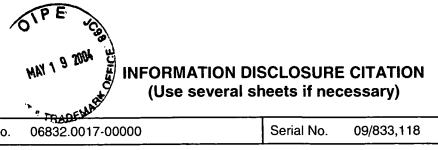
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